



## NV Microlaser & NV Ortho User's Manual

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This manual must be read thoroughly and understood prior to using the laser system. **CAUTION: Using the controls and adjustments or performing laser procedures, other than as specified herein, may result in hazardous radiation exposure.**

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## INTRODUCTION

The NV Microlaser is a dental diode laser that can be used for many different soft tissue procedures. Laser technology has enabled dentistry to provide less invasive treatment for many dental procedures, both preventative and restorative. The NV Microlaser/NV Ortho diode laser represent a new phase in dental laser technology. With its streamlined design, you can perform a range of soft-tissue procedures with ease, without worrying about fiber management and dealing with power cords. DenMat's diode laser was designed to be a compact wire-free laser that makes your day-to-day operations more efficient and productive. For a list of approved procedures, please refer to pages 4 and 18-19. All the controls you need are accessible on the handheld unit which, is lightweight and extremely mobile.

Choosing to integrate laser science into your practice yields many benefits, including increased patient comfort, satisfaction and more efficient dental care. To get the maximum benefits of laser technology, consider joining a study group so that you can exchange tips and ideas with fellow professionals.

The DenMat website, [www.denmat.com](http://www.denmat.com), also provides information on new products, accessories, and educational assistance for you and your professional staff. If you have any questions regarding the use of the diode laser, please call our toll-free support line. We're here to help.

## PRODUCT DESCRIPTION

The progress achieved in recent years in fiber optics and diode lasers technology has made it possible to have commercial devices with multi-watt output power in the near-infrared spectrum.

This laser technology is now being used in many areas of medicine and dentistry, particularly oral surgery, arthroscopy, gastroenterology, general surgery, dermatology and plastic surgery. The intended uses of these laser devices include hemostasis, incision, excision, ablation, vaporization, and coagulation of tissue. In dentistry, usage of laser devices ranges from cosmetic surgery to treating periodontal disease.

As the dental laser industry grows, there is an increased demand for portable soft tissue lasers. In today's market, customers want a more portable laser solution to avoid office clutter and to reduce set-up time. It has also become apparent that a relatively low-power laser (2.0 watts and 830 nm) covers virtually all laser surgical requirements. The NV Microlaser/ NV Ortho diode laser is the first soft-tissue laser developed as a handheld unit. It is wireless, lightweight, easy to set up, simple to use, requires less power, and is cost efficient.

With NV Microlaser/NV Ortho diode laser fiber accuracy is better than 5mm and the alignment is extremely stable. A module with a specific lens was developed in order to achieve such precision and alignment. This design greatly simplifies the fiber management and set-up of operatory time as the fiber is attached into the tip allowing this item to be disposable and simple to use. No fiber scoring is needed as the disposable tip is provided already scored to decrease set-up time and user error.



## INDICATIONS FOR USE

The NV Microlaser/NV Ortho diode laser is intended to be used for oral soft tissue surgery, including: sulcular debridement of diseased fibrous tissue, i.e., excision and biopsy; gingivectomy; gingivoplasty; lesion (tumor) removal; fibroma removal; tissue retraction (troughing); aphthous ulcers; gingival hyperplasia (excision and recontour); crown lengthening; operculectomy; frenectomy; and photocoagulation. In addition, the diode laser may be used for periodontal procedures, including: laser soft tissue curettage; laser removal of diseased, infected, inflamed, or necrosed soft tissue within the periodontal pocket; removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining; and junctional epithelium.

## SPECIFICATIONS

Dimensions of Charging Unit:	2.7" H x 2.9" W x 8.0" L
Dimensions of Laser:	6.9" L x 0.65" diameter
Weight:	1.9 ounces
Laser classification:	Class IV laser device
Delivery system:	Optical Fiber
Wavelength:	Laser 830nm $\pm$ 5nm
Maximum power:	2 Watts $\pm$ 20%
Aiming beam wavelength	650 $\pm$ 10nm
Aiming beam power	5mW max
Beam divergence:	617 mrad
Power range:	0.1 Watt to 2.0 Watts
Pulse frequency:	Fixed 10 Hz
Pulse duration:	Fixed 0.05 seconds
Duty cycle:	Pulsed mode 50% Continuous wave 100%
Audible notification:	Yes
Power requirements:	100-240 VAC @ 50 to 60 Hz
Current:	0.8 Amps
Battery:	Rechargeable lithium ion
20 minutes continuing lasing time @ 1.2 Watts	8 hours stand-by time
Wireless Foot Pedal frequency:	2.4 GHz
Foot Pedal Power source:	AA Batteries (provided)

### The NV Microlaser/NV Ortho diode laser complies with the following:

- IEC 60601-1
- IEC 60825-1
- 21 CFR 1040.10 and 1040.11
- FCC parts 15 and 18 (47 CFR)
- IEC 60601-2-22

# SETTING UP YOUR NV MICROLASER OR NV ORTHO

## Contents of the Laser Container

- 1 NV Microlaser/NV Ortho Main Body
- 2 Lithium Ion Batteries
- 3 Pairs of Safety Glasses
- 1 Base Charger (cradle)
- 1 Power Supply for the Charger
- 1 Wireless Foot Pedal
- 2 AA Batteries for the Foot Pedal
- 2 Boxes of 7 Disposable Tips
- Warranty Certificate and Caution sign
- 1 User's Manual
- 1 Pack of Carbon Film

## Laser and Charging Unit

The Laser and Charging Unit comprise the following major modules:

The laser diode assembly contains one single-emitter laser diode of 2.0 watt output power (Class IV laser) lasing at 830 nm. The diode laser is directly coupled to a lens and aligned to the fiber optic inside the removable tips, using a 2 axis alignment system (patent pending).

The NV Microlaser/NV Ortho diode laser is designed to dissipate heat during normal operation. The laser module is mounted towards the tip of the unit, which acts as a heat sink during normal operation. The temperature is monitored by a sensor that prevents overheating.

The laser power controller provides electric power to the diode in continuous wave and pulse mode. It supplies about 2 VDC and current up to 4A to the diodes. The controller contains a high efficiency DC to DC converter that converts the battery voltage to the precise voltage needed for laser operation. This ensures that the majority of the energy is used for light and not converted into heat.

The delivery tips with fiber built in consist of 400 micron core multi-mode, optical fiber, and a precise alignment mechanism. The fiber is factory installed into the tip and requires no installation by the end user.

The foot-switch is a (UL-approved) commercial foot-switch that provides hands-free ON/OFF capabilities. This switch controls initiation/termination of laser power wirelessly using 2.4GHz frequency. (Note: Some models come with a shrouded foot pedal)

## Delivery System Specifications

The delivery system is composed of a disposable, one-time use plastic tip with an optical quartz fiber built in. The optical fiber diameter is 400µm attached to a custom made steel connector that precisely attaches via a magnet onto the laser aperture component. The magnet acts as a guide with a precise tolerance for a unique fit of the disposable tip on to the laser unit.

## Unpacking the Container

No special assistance is required to unpack and assemble the NV Microlaser/ NV Ortho diode laser. However, if you have any questions or concerns, call DenMat at 1-800-4DENMAT.

Packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of unsafe product and it should not be used until carefully inspected. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination.

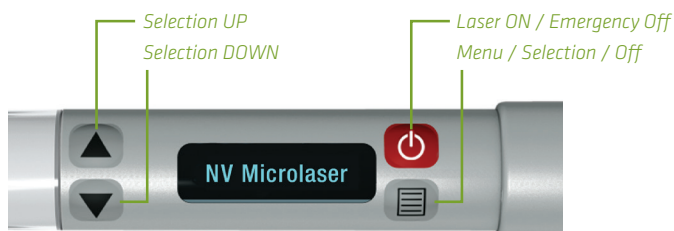
Note: The shipping container has been designed to safely transport the NV Microlaser/NV Ortho diode laser. We recommend that you keep the container in case you need to ship the laser back for service or repair.

## Charging the batteries

The NV batteries are partially charged when shipped. Before you turn on and start using your laser, you must fully charge all batteries before using your laser for the first time. Use only the approved charger that is included with your laser. Failure to follow these instruction may result in a voided warranty.

## Using the NV and NV Ortho

Assembling the diode laser is a simple process. The handheld laser consists of three pieces: the display and laser unit, the battery, and the disposable tip. You control the laser with the wireless foot pedal. When you are not using the laser, it rests in the cradle/battery charger.



## Laser Display Unit

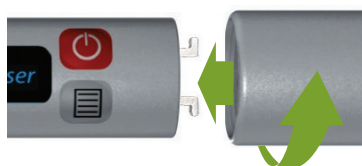
All operations and procedures are conveniently located on the laser OLED display unit. The red Power button turns the laser on and off. When you turn the laser on, the laser welcome screen will flash and will immediately display "Enter key \_\_\_\_." Press the up button in sequence four (4) times, until check marks fill in the blanks. This represents the correct password. The Menu button allows you to easily cycle through the various options. The Up and Down Arrow keys increase and decrease the power. You also use the arrow keys to scroll through the options when you are using one of the menus.

To store or recharge the laser, you must first remove the disposable tip. Place the laser flat in the slot by tipping it slightly up and inserting the end of the battery first and then lowering it into the slot. Do not place the laser upright in the vertical battery charging ports.

Recharging a completely discharged battery takes approximately 1 hour. The LED lights on the cradle indicate the amount of charge remaining. If the light is red, the battery is low. An orange light indicates an almost full charge. When the light is green, the battery is fully charged.

## Attaching the Lithium Ion Battery

The diode laser comes with two rechargeable lithium ion batteries, allowing you to always have a fully charged battery available. To attach the battery to the main body, match the two pins (male) located on the main laser body into the battery



*Line-up pins with holes on battery and twist clockwise to lock*

slot (female). Twist the battery clockwise until it firmly locks into place. The battery should lock in place and stay firm without any play. The battery provides up to 20 minutes of continuous operation at 1.2 watts of power when fully charged.

When you first unpack the laser, charge the battery for two hours or until the indicator light on the charger becomes green. The battery must be fully charged before initial use.

## Battery Disposal

Batteries contain toxic materials and should not be disposed of in landfills or incinerators. Dispose of depleted batteries as directed by your local solid waste handling regulations. To dispose of the battery, we recommend [www.call2recycle.com](http://www.call2recycle.com) to locate a recycling facility near you.

## Charging Unit

The charging unit securely stores the laser unit and charges the batteries at the same time. You can charge up to three batteries: two in the dedicated battery ports and one in the resting slot for the laser.

NOTE: The laser comes with two batteries. You may order additional batteries if desired.

Connect the provided power supply at the back of the charging unit. The power supply can be used in outlets of 100~240 VAC.



Replacement batteries are available for sale at [www.denmat.com](http://www.denmat.com).

NV Microlaser battery P/N: ZLR1010

NV Ortho battery P/N: ZLR1011

## Disposable Laser Tips

Each fiber tip is protectively wrapped in its own package. The fiber tips are pre-scored and pre-stripped. The tip must only be used for a single procedure and then properly disposed.

The tip slips easily onto the laser shaft, aligning on the ridges. The unit contains a strong magnet, which snaps the tip into place and aligns the tip with the laser aperture. When the tip is connected, there is visual verification indicating that the tip is properly attached and the laser unit is on standby waiting to be used.



You can attach the disposable tip in six different positions, allowing the user to reach difficult areas during surgical soft-tissue procedures.

NOTE: The disposable plastic hand piece tips are supplied non-sterile by the manufacturer and must be discarded in an infectious waste container (SHARPS) after each use. There is no re-use or re-sterilization procedure indicated.

NOTE: Steeply bending or improperly securing the fiber tip may lead to damage to the laser delivery system and/or harm the patient or user.

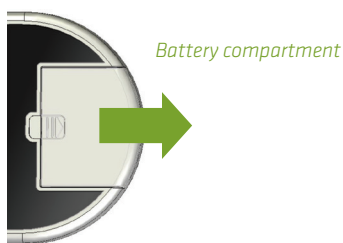
NOTE: If incorrect power supply is used the charger will not charge, and permanent damage may occur to the charger.

## Wireless Foot Pedal

The battery-powered wireless foot pedal is composed of a supporting plastic base plus the pedal which comes attached to the base. In order to power the foot pedal, you must insert the provided AA batteries that came with the laser. Before inserting the batteries, make sure that the laser is completely turned off and that the laser battery is not attached.

1. Turn the foot pedal upside down to locate the battery slot.
2. Remove the lid and insert the batteries.
3. Close the battery lid.

Note: Keep extra AA batteries in your office inventory because the battery should be replaced after 100 hours of continued operation. During use, if the red battery light comes on, the foot pedal batteries need to be charged.



## Software Lock

1. Firmly press the red power button alongside the OLED display.
2. The laser welcome screen will flash and will immediately display  
“Enter Key \_ \_ \_ \_”
3. Press the up (▲) button in sequence four (4) times , until four check marks fill in the blanks. This represents the correct password.

## MENU OPTIONS

You can control all operations by navigating through the Menu/Selection button. Press the Menu button to display the options. In addition, the same button is your selection button to be clicked when you want to make the selection. The main menu options are:

**Press 1x to show** - Laser Mode - choice of CW or Pulsed operation

**Press 2x to show** - Procedures - lists all pre-set procedures

**Press 3x to show** - Beep Volume - control the beeping intensity

To navigate through the options, simply press the Menu/Selection button. Within each menu, you can view the specific options by pressing the UP and DOWN Arrow keys. To make a selection, press the Menu/Selection button again.

## Selecting the Laser Mode

*Press Menu once for Laser Mode*



Press the Menu button 1x.

The display shows Laser Mode.

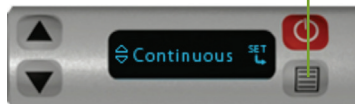
Move the arrow UP and DOWN to show your mode options.

In this case the first option to be shown is Continuous Wave Mode. Continue to click UP or DOWN to browse through the other modes. To make a selection, click the Menu/Selection button again.

*Use UP & Down arrows for modes*

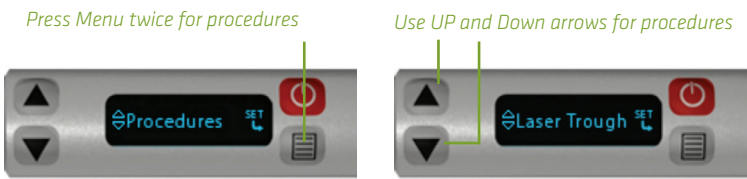


*Press Menu again to make selection*



# Selecting the Pre-Set Procedures

Press the Menu button 2x.



The display shows Procedures.

Move the arrow UP and DOWN to show your procedures options.

In this case the first option to be shown is Laser Troughing. Continue to click UP or DOWN to browse through the other procedures. To make a selection, click the Menu/Selection button again.

After selecting a procedure, you can manually adjust the power settings if needed by pressing the UP or DOWN arrows. The image below demonstrates the main power screen after a pre-set procedure is selected. It happens to be a continuous mode procedure. It also shows the battery is fully charged.

*Use UP and Down to control power output after a procedure selection is made*



A list of all 8 pre-set procedures is shown below in the order that they are displayed:

## NV Microlaser

1. Laser Troughing
2. Class V Restoration
3. Implant Recovery
4. Gingivectomy
5. Frenectomy
6. Biopsies
7. Aphthous-Ulcers
8. Laser Curretage

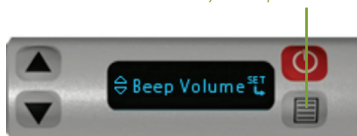
## NV Ortho

1. Cuspid Exposure
2. TAD Exposure
3. Gingivectomy
4. Frenectomy
5. Recontouring
6. Operculectomy
7. Aphthous Ulcers
8. Canker Sores

## Selecting the Beeping Volume

Press the Menu button 3x.

*Press Menu three times for beep volume*



*Use UP & Down arrows for modes*



The display shows Beep Volume.

Move the arrow UP and DOWN to show your beeping volume options (Low, Medium, High).

In this case the first option to be shown is Low. Continue to click UP or DOWN to browse through the other options. To make a selection, click the Menu/Selection button again.

## USING THE NV MICROLASER OR NV ORTHO

### Continuous Wave and Pulse Modes

The NV Microlaser/NV Ortho diode laser delivers laser energy in either a continuous wave (CW) or as timed pulses. Selecting the appropriate mode is important for controlling the temperature of the target tissue and using an efficient amount of energy. The pulse duration (0.05 seconds) and the number of pulses per second (10) are fixed and use a 50% duty cycle. The duty cycle is the percentage of time in each second that the laser is emitting energy. These settings cannot be adjusted.

NOTE: Because laser energy is attracted to melanin and hemoglobin, reduce the power when treating patients with darker soft tissue. When lasing, avoid penetrating or damaging the periosteum, and do not use the laser on alveolar bone. Make sure that the fiber tip has no shards. A shard can act as a miniature scalpel and damage the small blood vessels, thus preventing hemostasis and coagulation.

### Continuous Wave Mode

When the laser is in Continuous Wave (CW) mode, the amount of power that you set the laser to is the amount of power delivered.

CW mode is generally the fastest way to ablate tissues. However, heat can build up and damage the target and adjacent tissues. Cool the tissues using periodic blasts of air from a triplex syringe and high-speed suction. You may want to use water to

cool areas where there is prolonged exposure to the laser beam.

Do not use an air syringe when you have an opening in soft tissue adjacent to or within the surgery site. An air embolism may occur as a result of air captured within the tissue during the cooling process.

## Pulse Mode

Pulsing the laser energy allows some cooling of the tissue between energy emissions. The pulses per second, the duty cycle, and the energy intensity per pulse determine the average power emitted. In pulse mode, the diode laser is programmed to deliver ten pulses per second, with each pulse lasting 0.05 seconds. This results in an average power that is 50% of what you set the laser for. Therefore, when using pulsed energy, you must adjust your power upward to achieve the same rate of output as the same power set in CW mode. For Instance, 2 watts of pulsed power is the same average power output as 1 watt of continuous power.

## Operating the Laser

The following are the basic steps involved in using the NV Microlaser/NV Ortho diode laser. A pictorial representation of all the steps shown below can be seen on Pages 7 through 14.

### 1). Foot Pedal Assembly

- a). Insert the AA batteries (provided).
- b). The green light indicates that the foot pedal is in standby mode.

### 2). Base Charger Assembly

- a). Connect the power supply to the rear panel of the base charger.

### 3). NV Microlaser/NV Ortho Diode Laser Assembly

- a). Attach the lithium ion battery.
- b). Attach the disposable tip. You will see a verification on the OLED display when it is properly connected.
- c). Firmly press the red power button alongside the OLED display. The OLED display will light up, confirming the laser is on.
- d). The laser welcome screen will flash and will immediately display "Enter key \_ \_ \_ \_".
- e). Press the up button in sequence four (4) times, until four check marks fill in all the blanks. This represents the correct password.

- f). The display shows the power setting as 0.0W.
  - g). If the TIP symbol is displayed on the screen, it means the tip is inserted correctly and the laser unit is ready to fire.
- 4). Wearing Protective Eyewear
- a). Wear the appropriate wavelength-specific (OD>5 at 830 nm) eyewear for operator, assistants and patient.
- 5). Selecting the Desired Power
- a). Click the UP and DOWN arrows to make your selection.
- 6). Initiating the Tip
- a). If the procedure requires an initiated tip, increase the laser output power to its value of 0.6 by pressing the UP button a few times. With the tip of the fiber touch a piece of initiating film and depress the foot switch to activate the laser. When laser emission begins, move the tip back and forth over the surface. There will be a rapid melting/ vaporization of the film and the tip should now be dark.
- 7). Selecting a Laser Mode (Continuous Wave or Pulse)
- a). Press the Menu/Selection button until the display shows Mode.
  - b). Select the UP/DOWN arrows to find the desired mode.
  - c). Click the Menu/Selection button to make your selection.
- 8). Selecting a Pre-Set Procedure
- a). Press the Menu/Selection button until the display shows Procedures.
  - b). Select the UP/DOWN arrows to find the desired procedure.
  - c). Click the Menu/Selection button to make your selection.
- 9). Adjusting the Beeping Volume (Low, Medium, High)
- a). Press the Menu/Selection button until the display shows Beep Volume.
  - b). Select the UP/DOWN arrows to find the desired volume intensity.
  - c). Click the Menu/Selection button to make your selection.
- 10). Test the Laser Before Proceeding
- a). Always test the laser before inserting into the patient's mouth.
- 11). Perform the Procedure
- a). While pressing the foot pedal, use short quick strokes at the lowest power that you can to perform the treatment.
- 12). Discard the Tip

- a). When you are done, remove the disposable tip and discard in a biowaste SHARPS container.

**NOTE:** The disposable tip is a one-time use tip and cannot be reused or refurbished by any means. Attempting to reuse the disposable tip may cause malfunction of the diode laser device.

### 13). Place the NV Microlaser/NV Ortho in the Base Charger

- a). When not using the NV Microlaser/NV Ortho diode laser, rest it on the base charger. To prevent misuse, make sure the disposable tip is removed. Always charge the NV Microlaser/NV Ortho diode laser when the tip is not attached to the laser unit.

## OPERATING CONDITIONS AND SAFETY CONSIDERATIONS

### Treatment Area

Always use the laser in a well-lit and ventilated area. The area around the laser must be free of standing water. Chemicals or gases that could cause combustion must not be present when using the laser. Use a high-volume vacuum to remove the laser “plume.”

Provide high-filtration masks for all personnel in the treatment area. The laser plume may contain viable tissue particulates.

## SAFETY FEATURES

### Audible Lasing Signal

An audible signal (high-pitched buzzing) sounds whenever the activation foot-switch is depressed.

### Key Switch or Software Lock

Some systems are equipped with software and cannot be turned ON until the correct software key is inserted into the foot pedal. Systems with a software lock require proper code input prior to use (see pgs. 9 – 10)

### Laser Stop Button

The laser has a laser stop button in case the laser needs to be shut down immediately. The shutdown switch is the red button located on the main body. If the laser needs to be immediately shut down, press and release the red Power/Laser Stop Button.

### Enclosure Interlock

The laser system is protected by an enclosure interlock that will not allow electrical power to the unit if cover is removed.

### Remote Interlock

The remote interlock jack gives you the option of installing the NV Microlaser/NV

Ortho diode laser in a dedicated room and be interlocked with the entrance door to the room. In an interlocked installation, the laser shuts off whenever the door is opened, thereby protecting the eyes of the person entering the room.

Contact DenMat at 1-800-4DENMAT for more information or questions about the remote interlock.

### **Laser Firing Delay**

There is a brief delay between depressing the footswitch and the onset of the laser activation. This allows the user adequate time to react if the footswitch is inadvertently depressed or laser operation should be aborted.

### **Safety Eyewear**

The laser beam can cause eye damage when misused. When using the laser, everyone in the treatment area must wear safety eyewear with an optical density (OD) of 4 or better, which are designed for use with a 830 nm wavelength. The laser tip should never be pointed directly at the face, eyes, or skin. The nominal ocular hazard distance (NOHD) is 902mm. While wearing OD-4 eye protection the NOHD is reduced to 9.2mm.

### **Safety Signage**

When a laser procedure is in process, place a Laser in Use sign at the entrance of the room to warn staff to be careful about entering. This warning can help avoid eye damage caused by inadvertent exposure to the laser.

### **Disposing of Fiber Tips**

Used fiber tips and remnants should be placed in a SHARPS container. Sponges used for cleaning up fibers should be disposed of in a bag for contaminated soft products.

### **Storage and Operating Conditions**

Storage temperature should be between 0°C and 50°C

### **Shelf Life**

The shelf life of the NV Microlaser and NV Ortho is 5 years

### **Undesirable Side Effects**

- a) Temporary transient discoloration as with the thermal energy at the tissue surface
- b) Possible discomfort during healing and tissue recession

### **Contraindications**

All clinical procedures performed with the NV Microlaser or NV Ortho must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical

treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, and immune deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

Not suitable for use in or around an MRI

Do not use in an oxygen tent

Power of performance loss

In the event the laser has a loss of power or performance, please stop using the laser immediately and contact DenMat Customer Service at 1-800-4DENMAT.

## PROCEDURES GUIDE

In order to better assist you with your procedures needs, we created a spreadsheet to guide you with the most conservative power of the following procedures. The settings shown below are for your guidance only.

Procedure	Technique	Mode	Power
Abscess	Contact	Continuous	1.0 W
Aphthous Ulcer	Non-contact	Pulse	1.4 W
Biopsy	Contact	Continuous	1.0 W
Contouring	Contact	Continuous	1.0 W
Distal Wedge	Contact	Continuous	1.5 W
Draining Abscesses	Contact	Continuous	0.9 W
Expose Teeth	Contact	Continuous	1.0 W
Fibroma	Contact	Continuous	1.0 W
Frenectomy	Contact	Continuous	1.1 W
Gingivectomy	Contact	Continuous	1.0 W
Gingivitis	Contact	Continuous	0.4 W
Gingivitis Therapy	Contact	Continuous	0.8 W
Gingivoplasty	Contact	Continuous	1.0 W
Hemostasis	Contact	Continuous	1.3 W
Herpetic Lesion	Non-contact	Pulse	1.6 W
Hypertrophic Tissue	Contact	Continuous	1.5 W
Implant Exposure	Contact	Continuous	1.4 W
Lesion Removal	Contact	Continuous	1.0 W

Operculectomy	Contact	Continuous	1.5 W
Ovate Pontic	Contact	Continuous	1.0 W
Periimplantitis	Contact	Continuous	1.0 W
Socket Treatment	Non-contact	Continuous	0.8 W
Sulcular Debridement	Contact	Continuous	0.8 W
Tissue Tag	Contact	Continuous	1.5 W
Tissue Welding	Contact	Continuous	0.6 W
Tongue Tie	Contact	Continuous	1.0 W
Troughing	Contact	Continuous	0.8 W
Vestibuloplasty	Contact	Continuous	1.0 W

## Hard Tissue Procedures

The NV Microlaser/NV Ortho diode laser is not intended to be used for hard tissue procedures. The diode laser is attracted to melanin, hemoglobin and, to some extent, water and oxygenated hemoglobin. Avoid prolonged exposure when working in and around the cervical areas of the tooth. Because of the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp, and pulpal hyperemia may occur. Extended exposure to laser energy could cause pain and pulpal necrosis.

## LABELS, SIGNS, WARNINGS, AND SAFETY FEATURES

### Danger Laser in Use

Each treatment area should have a "Laser In Use" warning sign posted at the entrance of the treatment area. This signage serves to warn people not to enter the treatment area without proper safety eyewear and protective clothing when the laser is in use.

### Interface and Wireless Signal

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause the user to correct the interference at his/her own expense.

## Device Precautions

**CAUTION!** Changes or modifications not expressly approved by DenMat could void the user's authority to operate the equipment.

**CAUTION!** Laser Radiation- Avoid exposure to the eyes or skin from direct or scattered radiation.

**CAUTION!** This product contains no user serviceable components within the chassis. Visible and invisible radiation may be present when the cover is removed. Do not open the laser chassis under any circumstances.

**CAUTION!** US Federal law restricts this device to sale by or on the order of a licensed dentist. This product is for use by authorized personnel only.

**CAUTION!** Eyewear that protects your eyes from wavelengths other than 830 nm do not provide proper protection for use with this laser. Damage to the retina or cornea may be irreparable if exposed to direct, reflected or scattered radiation. Always wear protective eyewear when operating the laser.

**CAUTION!** Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

**CAUTION!** Do not attempt to remove the cover from the laser chassis for the purpose of repairing the laser. Serious injury from electrical shock or laser radiation could occur. Removing the cover on the laser chassis will void the warranty.

**CAUTION!** Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, the laser's energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to laser energy could lead to pain and possible pulpal necrosis.

**CAUTION!** A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment. The high temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen.

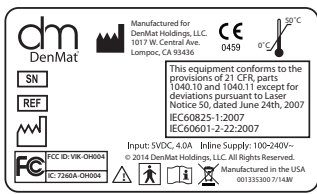
**CAUTION!** LASER equipment not in use should be protected against unqualified use. The laser must be installed and operated according to CAN/CSA-Z386-92: Laser safety in health care facilities.

LABELS AND SYMBOLS

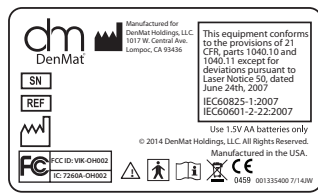
Aperture Label:



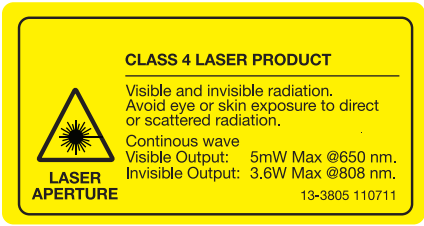
Base Charger Label



Foot Pedal Label




Caution Label:




Laser Aperture:







Consult instruction manual for use




50°C  
0°C  
Temperature limits




Dispose of properly




Manufacturer




Professional use only




Manufacture date




Caution




Fragile




Type BF applied part




Do not use if package damaged




Keep dry




EU Representative



Serial number



Catalog number



Non-ionizing radiation

## MANUFACTURER'S INFORMATION

### Cleaning and Disinfection Instructions

The NV Microlaser/NV Ortho diode laser is not supplied in sterile condition, nor must it be sterilized before use. The following disinfecting procedures are recommended for the following fixtures and attachments to the device before the initial and after each subsequent use:

The disposable plastic hand piece tips are supplied non-sterile by the manufacturer and are to be discarded in an infectious waste container (SHARPS) after each use. There is no re-use or resterilization procedure indicated.

Caution should be taken when disinfecting the laser to avoid damaging the external and internal electrical components. If using a liquid disinfectant apply to a gauze or soft cloth and then wipe down the laser. Do not use abrasive materials to clean the laser. Place a protective barrier material such as cellophane over the control panel and LED screen prior to treating the next patient. Failure to follow these instruction may result in a voided warranty.

**DO NOT** spray the disinfectant directly on the laser unit, because it could damage the OLED display.

**DO NOT** use abrasive materials to clean the laser.

### Calibration

We suggest that your practice establish an internal verification program for your laser. Verification is recommended a minimum of once per year based on average usage. You may purchase a calibrated hand-held power meter approved for use with 830 nm devices to check power output. The laser should be set in continuous wave mode. The NV Microlaser and the NV Ortho diode laser should be set at 0.5, 1.0 and 1.5 Watts with the output checked at each level. The output display should be within 20% of the meter reading. If not, replace the tip and re-check. If the output display is outside the 20% tolerance, return the unit to the manufacturer for recalibration.

## COMPLIANCE

### FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This product has been tested and complies with the specifications for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed

to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used according to the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which is found by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment or devices
- Connect the equipment to an outlet other than the receiver's
- Consult a dealer or an experienced radio/TV technician for assistance

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

### Industry Canada Statement

This Class B digital apparatus complies with Canadian ICES-003 and RSS210.

Operation is subject to the following two conditions:

1. This device may not cause interference and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

## WARRANTY POLICY

Seller warrants the Products to be free from defects in materials and workmanship for a period of twelve months from the date of shipment, except for consumables. If within such period any Products shall be proved to Seller's satisfaction to be defective, it shall be (i) repaired using new or refurbished parts, or (ii) replaced with a new or refurbished product, at Seller's sole discretion. Such repair or replacement shall be Seller's sole obligation and Buyer's exclusive remedy under this Warranty and shall be conditioned, at Seller's option, upon return of such Products to Seller, f.o.b. its factory. This Warranty only covers Product issues caused by defects in material or workmanship during ordinary consumer use; it does not cover Product issues caused by any other reason, including but not limited to acts of God, modifications of or to any part of the Product, improper testing, assembly, mishandling, or improper operation contrary to current instructions relating to installation, maintenance or operation, or contrary to industry standards relating to acceptable input power. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED; AND SELLER EXPRESSLY DISCLAIMS AND EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. SELLER SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON THIS PRODUCT.

### Repairs and Returns to DenMat

Should the laser fail to operate correctly please call DenMat Customer Service TOLL FREE PHONE NUMBER 1-800-4DENMAT to obtain a Return Authorization (RA) number for shipping purposes.

No lasers will be accepted without an RA. Please ensure that the RA number is clearly marked on the box used to return the laser. It is recommended that you return your laser in its original shipping box. If the original shipping box is not available, make sure that adequate packing is used to protect against shipping damage. Make sure you buy insurance to protect your asset against shipping damage. Please clearly state the reasons for your return.

### Send Returns To:

Attention: Laser Repair Manager

DenMat Repair Department

1017 W. Central Ave., Lompoc, CA 93436

\*Return labels will be provided with RA number by our Customer Service Department.

**GUIDANCE AND MANUFACTURER’S DECLARATION-  
ELECTROMAGNETIC EMISSIONS**

The NV Class IV Soft-Tissue Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the model NV should assure that it is used in such an environment.

Emission	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The NV uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The wireless transmitter in the foot pedal is battery powered only and does not connect to public mains.
RF emissions CISPR 11	Class A	The NV is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Power Line Harmonics IEC/EN 61000-3-2	Class A	
Power Line Flicker IEC/EN 61000-3-3	Complies	

Warning: This equipment/system is intended for use by dental professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the NV or shielding the location.

# **GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY**

The NV Class IV Soft-Tissue Diode Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model NV should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electronic Discharge (ESD) IEC 6 1000-4-2	Air ± 8 kV Contact ± 6 kV	Air ± 8 kV Contact ± 6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 6 1000-4-4	Power line ± 2 kV I/O lines ± 1kV	Power line ± 2kV No I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6 1000-4-5	±2kV Line(s) to earth	±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 1kV Lint to Line	±1kV differential mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 6 1000-4-11	>95% dip in UT for 0,5 cycle	>95% dip in UT for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NV requires continued operation during power mains interruptions, it is recommended that the NV be powered from an uninterruptible power supply or a battery.
	60% dip in UT for 5 cycles	60% dip in UT for 5 cycles	
	30% dip in UT for 25 cycles	30% dip in UT for 25 cycles	
	>95% dip in UT for 5 seconds	>95% dip in UT for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC 6 1000-4-8	3 A/m at 50 Hz	3 A/m at 50 Hz	If image distortion occurs, it may be necessary to position NV further from sources of power. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE: UT is the AC mains voltage prior to application of the test level.

# GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The NV Class IV Soft-Tissue Diode Laser System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model NV should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Actual IMMUNITY LEVEL	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the NV, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d=1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1,2\sqrt{P}$ 80 MHz to 800 MHz $d=1,2\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by and electromagnetic site survey, a should be less than the compliance level in each frequency range.

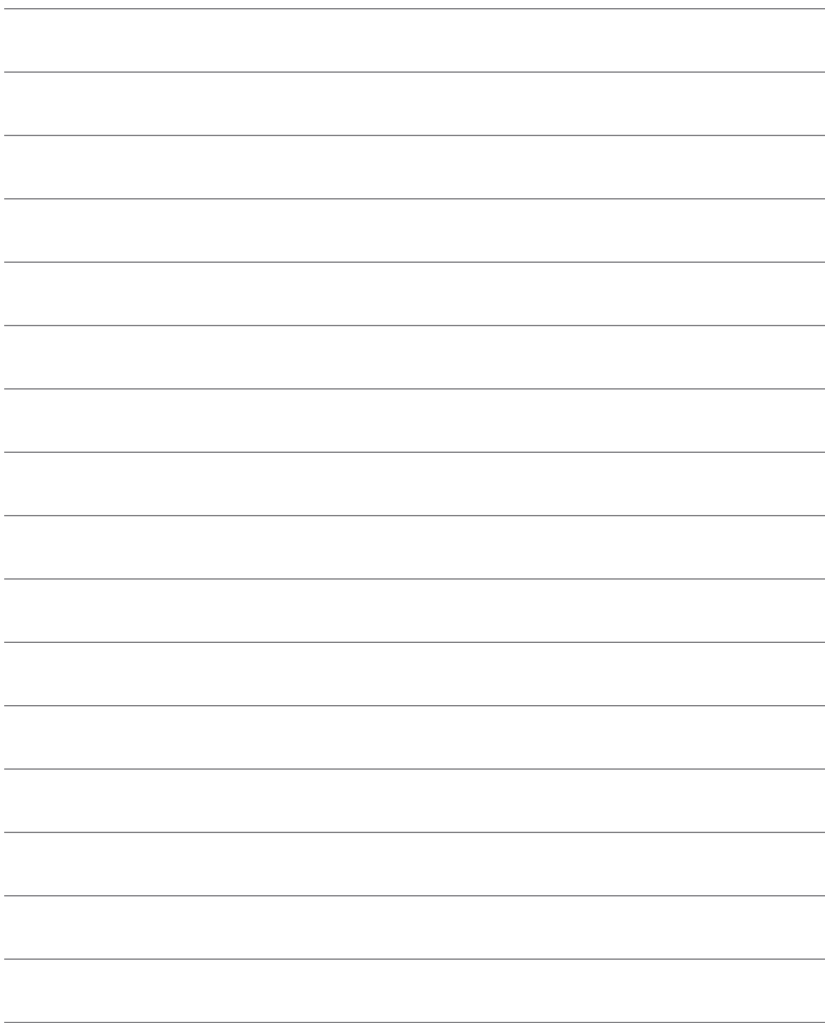
NOTE 1: At 80 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NV is used exceeds the applicable RF compliance level above, the NV should be observed to verify normal operation. If abnormal performance is observed, the additional measures may be necessary, such as re-orienting or relocating the NV.
- b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Notes

[illegible]





0459

MDSS GmbH  
Schiffgraben 41  
30175 Hannover  
Germany



Manufactured for  
DenMat Holdings, LLC  
1017 W. Central Ave.  
Lompoc, CA 93436

1-800-4DenMat  
(1-800-433-6628)  
[www.denmat.com](http://www.denmat.com)

